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A5R RGE

(56) Documents Cited
EP 0404516 A WO 89/05671 A WO 89/04674 A
WO 89/03232 A US 4479795 A

(58) Field of Search
UK CL (Edition K) A5R RGE
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(54) Catheter with porous matrix material

(57) A catheter for drainage or collection of a bodily fluid comprises a tube (10) having openings at its two opposed ends and having, within the tube, a matrix such as a plug (18) in the form of a porous or potentially porous material containing one or more medically beneficial substances such as a urease inhibitor, antibacterial agent or mineral formation inhibitor. The matrix may be permanently located within the structure to adsorb or absorb bodily fluids and thereby permit controlled release of the beneficial substances. Alternatively, the matrix may be in the form of a surface coating (20) of porous material containing the beneficial substance or a rod (26) of the substance surrounded by a tube (28) of porous material may be in communication with a central drainage channel (24).

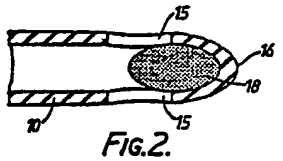

FIG.2.

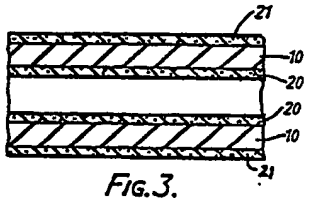

FIG.3.

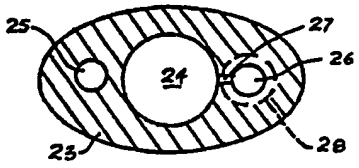

FIG. 4.

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

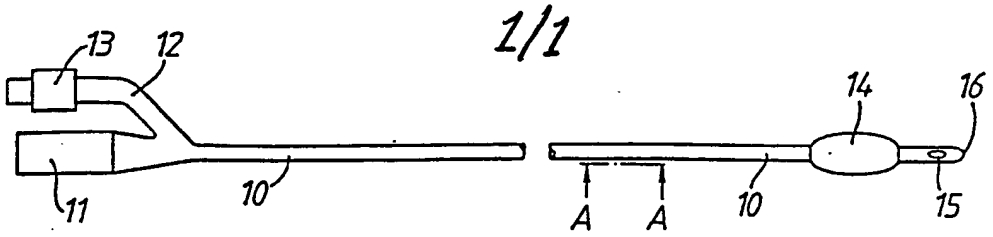

FIG. 1.

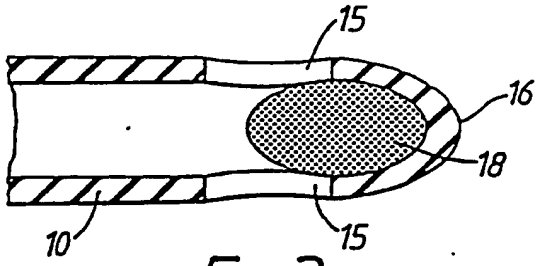

FIG. 2.

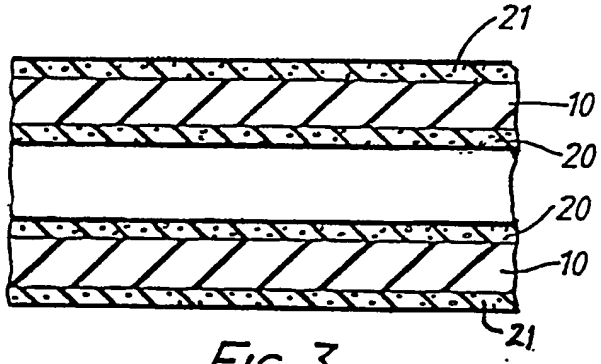

FIG. 3.

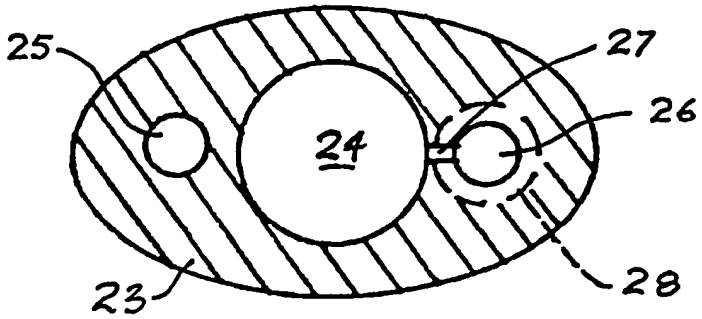

FIG. 4.

A CATHETER

THIS INVENTION relates to catheters, in particular to medical catheters such as those used for the drainage or collection of a bodily fluid. A common example of the use of such catheters is to drain urine from the bladder, and they may be in place for prolonged periods during which it is beneficial to modify the composition of the bodily fluid, for example, to prevent problems which might otherwise occur.

In the case of urinary catheters, a common problem involves colonisation of the catheter by bacteria, and the formation of encrusting deposits. Furthermore, in applications where the catheter is used for the introduction of fluid into the body, it is important that the catheter itself does not become a source of infection.

The formation of encrusting deposits and/or colonisation of bacteria in urinary catheters can be reduced by the continuous release of anti-bacterial agents such as chlorhexidine, urease inhibitors such as acetohydroxamic acid, mineral formation inhibitors such as diphosphonates, and acids such as citric acid.

Beneficial agents of this kind could be released separately or simultaneously into the urine to avoid the problems of colonisation and deposition.

In published international patent application WO 89/05671, such beneficial substances are incorporated into a biodegradable plug or lining within the catheter, and the substances are released gradually by decomposition of the biodegradable material during use of the catheter. In this way the beneficial substances are released in a controlled manner during a substantial part of the period during which the catheter is in use.

An object of the present invention is to provide in a catheter of this kind a permanent supporting matrix which is non-biodegradable and which contains one or more beneficial substances in such a way that they may be released in a controlled manner.

According to the present invention a catheter for drainage or collection of a bodily fluid, which catheter comprises a tube having openings at its ends, is characterised in that in at least a part of the tube to be exposed in use to a bodily fluid, there is provided a matrix of a porous or potentially porous material containing one or more medically beneficial

substances.

Preferably, the matrix is permanently located within the structure of the catheter and is capable of adsorbing or absorbing a bodily fluid thus to permit the beneficial substance or substances to become dissolved therein and released from the matrix at a controlled rate.

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a general view of a tubular catheter of a conventional kind which may incorporate a supporting matrix in accordance with the invention;

Fig. 2 is a sectional view of the proximal end or tip of the catheter as shown in Fig. 1 and illustrating a supporting matrix permanently located therein;

Fig. 3 shows in longitudinal cross-section a portion of a catheter of generally similar type to that shown in Fig. 1 but having a different configuration of supporting matrix from that illustrated in Fig. 2. The portion illustrated in Fig. 3 is taken from a position equivalent to that indicated by lines A-A in Fig. 1;

and Fig. 4 is a diagrammatic transverse cross-section of a catheter in which a supporting matrix is provided in a different manner from that illustrated in Figs. 2 and 3.

The catheter shown in Figs. 1 and 2 comprises a tube 10 of , for example, nitrile rubber latex or silicone having a connector 11 for attachment to a drainage bag (not shown) and an inflation connector 12 with associated valve 13, for use in the inflation of a retention balloon 14. The tube 10 has two eye holes 15 adjacent its proximal end 16 so as to permit urine drainage into the tube 10.

Referring now to Fig. 2, there is permanently located in the proximal end 16 a plug 18 of a porous material whose pores are at least partially filled with a medically beneficial substance such as, for example, a urease inhibitor which may be acetohydroxamic acid. As discussed earlier in this specification, the beneficial agent may additionally or alternatively be in the form of a anti-bacterial agent or a mineral formation inhibitor, or other bodily beneficial substance. A plurality of such substances may be included, in separate locations or combined throughout.

The plug 18 may be secured in place by the complementary shapes of its outer surface and the tube inner surface, and/or by an acrylic adhesive or the like on the said surfaces. The plug protrudes slightly into the urine channel provided by the eye holes 15 and tubes 10, which ensures good contact between the plug 18 and the urine flowing through the channel.

The catheter tube 10 may be a size 16 Charrière unit with an internal diameter of 2.7 mm, and the eye holes having an axial length of 6.7 mm, whilst plug 18 has a volume in the region of 15 mm^3.

Once the catheter has been inserted into the urethra and urine enters the drainage lumen the urine is adsorbed or absorbed by the porous plug and so dissolves the beneficial substance causing it to diffuse out of the porous material and into the drainage channel.

In effect, the supporting matrix provided by the plug 18 defines a containment zone such that the beneficial substance is physically and/or chemically retained therein to provide a controlled release over the period when the catheter is in situ. Such period is typically about 14 days, and it is desirable that the catheter be withdrawn as soon as the beneficial substances is entirely released.

Whilst the material of the supporting matrix may be naturally porous and may, for example, be a foamed polymeric material, the said material may become porous by dissolution of the beneficial substance itself which is initially dispersed within a generally non-porous material.

Referring now to Fig. 3 there is shown a generally similar construction to that shown in Fig. 1, but instead of the supporting matrix being in the form of the plug 18 as in Fig. 2, in this case the tube 10 has an inner and outer coating 20 and 21 respectively of latex foam or other porous or potentially porous material and containing the required beneficial substance.

Once again, the substances are released from the porous layers 20 and 21 by the infusion of one or more bodily fluids dissolving the beneficial substance. In some cases, only the inner layer 20 will be required for the release of the substance, the outer layer 21 being omitted.

Again, on a typical size 16 Charrière catheter the inner and outer layers 20 and 21 will preferably have a thickness in the region of 100µm

whilst the wall of the tube itself may be in the region of 1-2 mm in thickness.

Referring now to Fig. 4, there is illustrated an embodiment wherein the main structure of the catheter wall is shown at 23 and defines a central drainage channel 24 an inflation channel 25 and an inset "rod" 26 of a medically beneficial substance or of a porous material such as foamed latex containing the beneficial substance. In this instance, either a continuous slot 27 or a plurality of longitudinally spaced separate passages are provided through which bodily fluids from the drainage channel 24 may diffuse thus to dissolve and release the beneficial substance.

Yet again, in a further alternative, the rod 26 may be formed entirely from the beneficial substance and be surrounded by a porous supporting tube as illustrated by the dotted line 28, and which again is in communication with the drainage channel 24.

Whilst the cross-sectional shape of the catheter in Fig. 4 has been shown as elliptical, so as to conform to the natural shape of the urethra, for manufacturing convenience, it may be circular.

In all of the embodiments described, the porous material may form part of the normal

construction of the catheter, or be present as a lining or a plug which is securely fixed within the catheter.

CLAIMS

1. A catheter for drainage or collection of a bodily fluid, which catheter comprises a tube having openings at its ends, characterised in that in at least a part of the tube to be exposed in use to a bodily fluid, there is provided a matrix of a porous or potentially porous material containing at least one medically beneficial substances.

2. A catheter according to Claim 1, wherein the matrix is permanently located within the structure of the catheter and is capable of adsorbing or absorbing a bodily fluid thus to permit the medically beneficial substance to become dissolved therein and released from the matrix at a controlled rate.

3. A catheter according to Claim 1 or Claim 2, wherein said matrix is provided in the form of a plug of porous material located in the proximal or inner end of the catheter, and whose pores are at least partially filled with said medically beneficial substance.

4. A catheter according to Claim 1, wherein the beneficial substance is a urease inhibitor.

5. A catheter according to Claim 1, wherein the beneficial substance is an anti-bacterial agent.

6. A catheter according to Claim 1, wherein the beneficial

substance is a mineral formation inhibitor.

7. A catheter according to Claim 3, wherein the plug is secured in place by the complementary shapes of its outer surface and of the tube inner surface.

8. A catheter according to Claim 3, wherein the plug is secured in place by an adhesive.

9. A catheter according to Claim 3, wherein the plug protrudes partially into the urine channel thus to ensure contact in use between the plug and the urine flowing through the channel.

10. A catheter according to Claim 3, wherein the plug has a volume in the region of 15 mm^3.

11. A catheter according to Claim 1, wherein the matrix is formed from a foamed polymeric material.

12. A catheter according to Claim 1, wherein the matrix is formed from a generally non-porous material which becomes porous by dissolution of the beneficial substance contained therein.

13. A catheter according to Claim 1, wherein the matrix is in the form of a coating superimposed on at least the internal surface of the tube.

14. A catheter according to Claim 13, wherein said coating is formed from latex foam.

15. A catheter according to Claim 13, wherein said coating is formed from a generally non-porous material which includes the beneficial substance dispersed therein, such material, in use, becoming porous by the dissolution of the beneficial substance.

16. A catheter according to Claim 13, wherein the matrix is further provided as a coating superimposed on the external surface of the tube.

17. A catheter according to Claim 13, wherein the coating has a thickness in the region of 100μm.

18. A catheter according to Claim 1, wherein the matrix extends along the tube as a rod or tube disposed substantially parallel to the fluid channel and in communication therewith through one or more passages.

19. A catheter according to Claim 1, wherein the main structure of the catheter wall defines a central fluid channel, an inflation channel, and an inset "rod" of a medically beneficial substance or of a porous material such as foamed latex containing the beneficial substance.

20. A catheter according to Claim 19, wherein the rod is formed entirely from the beneficial substance and is surrounded by a

porous supporting tube the latter being in communication with the fluid channel.

21. A catheter for drainage or collection or a bodily fluid, substantially as hereinbefore described with reference to and as illustrated in Fig. 1 and any one of Figs. 2, 3 and 4 of the accompanying drawings.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

Application number
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Relevant Technical fields

(i) UK Cl (Edition K) A5R (RGE)

(ii) Int Cl (Edition 5) A61L, A61M

Search Examiner
L V THOMAS

Databases (see over)

(i) UK Patent Office

(ii)

Date of Search
15 OCTOBER 1992

Documents considered relevant following a search in respect of claims 1 TO 21

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	EP 0404516 A (BEIKTON DICKINSON) see lines 37-49 page 2 and lines 7-16 page 4	1, 19
X Y	WO 89/05671 A (BARD LTD ET AL) see line 29 page 3 - line 7 page 4 and line 31 page 4 - line 6 page 5	1,2,11, 13,14 4,6
X Y	WO 89/03232 A (BUKH MEDITEC) see line 15 page 4 - line 33 page 5, lines 14-21 page 6 and lines 5-21 page 16	1-3,5, 7-9,12 4,6
X	WO 89/04674 A (BIOCON) see line 23 page 6 - line 28 page 7, lines 1-20 page 12 and lines 13-23 page 13	1,2,5,11
X	US 4479795 (MUSTACICH ET AL) see line 65 column 4 - line 41 column 5 and lines 42-68 column 13	1,2,5,12

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

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